

REMARKS

The present application relates to inbred maize plant and seed PH48V. Claims 1-30 are pending in the present application. Claims 19-22 have been amended and claim 30 has been canceled. No new matter has been added by way of amendment. Applicant respectfully requests consideration of the claims in view of the following remarks.

Detailed Action

Applicant acknowledges that because this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant further acknowledges that Applicant's submission filed on October 17, 2005 has been entered.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 19-24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 19 and 23-24, the Examiner states the claims "are indefinite in their recitation of 'plant of claim 11 . . . further defined as . . . comprising a single locus conversion [or a gene or a transgene]'. It is confusing to characterize the plant of claim 11, which has a finite and particularly defined genome comprising a particular allele at every individual locus, as simultaneously comprising additional transgene or single locus conversions." The Examiner additionally states that it is "confusing to characterize the male fertile plant of claim 11 as simultaneously male sterile." See Office Action, p. 2

Applicant respectfully traverses this rejection. The Specification teaches that a gene conferring male sterility can be introduced into a maize plant using techniques well known in the art. (See Specification, p. 2, l. 24-p. 3, l. 9; p. 20, ll. 15-30) One skilled in the art would thus recognize that Applicant had adequately described claims 23 and 24.

Further, claims 19 and 23-24 depend from claim 11, which is adequately described and enabled. Claim 11 has been deemed allowable by the Examiner. Although not acceding to the Examiner's rejection, in an effort to expedite prosecution Applicant has

amended claim 19 to read "single gene conversion", further defining the claims. Applicant respectfully submits that one skilled in the art would thus recognize that Applicant has adequately defined claims 19 and 23-24.

Regarding claim 22, the Examiner states the claim is "indefinite in its recitation of 'yield enhancement' and 'improved nutritional quality' as these are relative terms for which no comparative standard is provided." *See Office Action, p. 3.*

Applicant respectfully traverses this rejection. "Yield Advantage" is defined in the specification as "the yield advantage of variety #1 over variety #2". (Specification, p. 14, ll. 9-10). Therefore yield enhancement would be the improvement of the trait yield over another variety. Applicant asserts that genes which increase yield by increasing the plants resistance to disease, herbicides, or insects are within the scope of the claims as presented.

Similarly, "improved nutritional quality" would represent an improvement in the nutritional quality versus another variety as described on page 20 of the specification. Further, single genes that affect nutritional quality are known in the art. Specifically genes for modified fatty acids, decreased phytate content and modified carbohydrate compositions are disclosed in the specification. (Specification, p. 31, ll. 10-31). Applicant respectfully submits that one skilled in the art would thus recognize that claim 22 is adequately defined.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

A. Written description regarding Claim 30

Claim 30 stands rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that the "claim is drawn to a plant breeding method comprising obtaining a molecular marker profile of the exemplified inbred, inducing doubled haploidy of F1 hybrid seed produced from the inbred, and then selecting

progeny that retain the molecular marker profile of the exemplified inbred. However, no basis in the specification was provided for these terms". See Office Action, p. 3

In an effort to expedite prosecution, Applicant has canceled claim 30, thereby alleviating this rejection.

B. Written description regarding Claims 1-10, 13-16 and 18-30

Claims 1-10, 13-16 and 18-30 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states the rejection is repeated for claims 1-10 and applied to new claims 13-16 and 18 for the reasons of record set forth in the Office Action of December 23, 2004. The Examiner further states that claims 25-30 are included "because they are drawn to methods of using uncharacterized descendants of the exemplified inbred in a multitude of outcrossing steps to uncharacterized breeding partners." See Office Action, pp. 3-4

Applicant respectfully traverses this rejection. Applicant reiterates that the written description requirement of § 112, first paragraph has been fulfilled by depositing seeds of PH48V in a public depository and by referencing the deposit in the specification (p. 50, ll. 2-27). See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). (stating that the written description requirement of § 112, ¶ 1 may be fulfilled by depositing material in a public depository, where the deposited material is not accessible in writing, and where reference to the deposit is made in the specification). This deposit not only describes inbred maize line PH48V but also the hybrid maize plants, plant parts, and seeds grown of claims 1-10, 13-16 and 18-30. In a prior case before the Board of Patent Appeals and Interferences, the Board determined that where an inbred maize plant had been deemed allowable, claims to the F1 hybrid seed and plants resulting from a cross between the allowable inbred maize plant and another inbred maize plant satisfied the written description requirement. See *Ex parte Carlson* (B.P.A.I. 2005). The Board therein stated:

All that is required by the claims is that the hybrid has one parent that is a plant of corn variety [inbred]. Since the examiner has indicated that the seed and the plant of the corn variety [inbred] are allowable . . . there can be no doubt that the specification provides an adequate written description of this corn variety. In addition, the examiner appears to recognize (Answer, page 25) that appellant's specification describes an exemplary hybrid wherein one parent was a plant of the corn variety [inbred]. . . Accordingly, it is unclear to this merits panel what additional description is necessary.

Ex parte Carlson, p. 16. Here, the Examiner has indicated that claim 11, directed towards a plant having all the morphological and physiological traits of PH48V wherein PH48V was deposited with the ATCC, is allowable. Accordingly, the genus of hybrid plants and seeds encompassed by claims 1-10, 13-16 and 18-30 are as well.

Applicant reiterates that each member of the genus of hybrids which has PH48V as a parent and which is encompassed by claims 1-10, 13-16 and 18-30 shares the identifying structural feature of the cells and/or chromosomes of inbred line PH48V. An Applicant's claims are described where they set forth and define "structural features commonly possessed by members of the genus that distinguish them from others." *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406 (emphasis added). One of skill in the art, utilizing technology well known in the art, could identify any member of the claimed genus. This is sufficient to meet the written description requirement. See *Id.* at 1568, 1406 (stating that with a fully described a genus, one skilled in the art can "visualize or recognize the identity of the members of the genus.")

Further, Applicant reiterates that the specification contains examples of the hybrids produced by PH48V in the application as filed. (Specification, p. 42, Table 3; pp. 43-49, Tables 4A-4E). A representative number of hybrids produced by utilizing PH48V as one of the inbred parents have accordingly been described. See *Regents of University of California*, 119 F.3d at 1569, 43 U.S.P.Q.2d at 1406 (stating that an Applicant "[is] not required to disclose every species encompassed by their claims even in an unpredictable art").

The Examiner states that new claims 19-21 and 19-24 are rejected because "they are drawn to plant comprising a multitude of uncharacterized single locus conversions or transgenes" and "because they are directed to plants which comprise a finite and completely

characterized genome and which exhibit a finite set of traits, and which simultaneously comprise additional genes conferring additional traits". See Office Action, p. 4.

Applicant respectfully traverses this rejection. The relevant claimed subject matter in claims 19-24 is the plant of claim 11 comprising a transgene or gene conversion. The Examiner has indicated that claim 11 is allowable. The specification teaches multiple ways of introgressing or transforming a maize plant with various genes which encode specific protein products which confer advantageous traits desired in the plant. (See Specification, p. 22, l. 1-p. 33, l. 28). The specification also teaches multiple transgenes that could be inserted into the plant of claim 11. (See Specification, p. 27, l. 19-p. 31, l. 31). Applicant further notes that the claims are specifically drawn to a single gene conversion, and that phenotypes resulting from multigenic interactions are not the subject matter of these claims. For example, numerous exemplary transgenes for improved nutritional quality are taught on page 31 of the specification. There are many examples of single gene conversions which effect nutritional quality, see for example, as taught in the specification transforming a plant with an antisense gene of stearoyl-ACP desaturase to increase stearic acid content of the plant (page 31, lines 10-12), introduction of a phytase-encoding gene that would enhance breakdown of phytate, adding more free phosphate to the transformed plant (page 31, lines 14-17). In addition, see U.S. Patent No. 5,936,145, issued August 10, 1999, which is prior to the filing date of the instant application. Claim 39 reads as follows: "[t]he single gene conversion of the corn plant of claim 29, where the gene confers enhanced yield stability". Thus, a single gene that confers enhanced yield stability was known in the art prior to the filing date of the instant application. One of skill in the art would recognize that it is common to transform a maize plant with various genes in order to confer desired traits to the maize plant.

The Examiner further states that claims 25-30 are included "because they are drawn to methods of using uncharacterized descendants of the exemplified inbred in a multitude of outcrossing steps to uncharacterized breeding partners." See Office Action, p. 4

Applicant respectfully traverses this rejection. Claims 25-30 are directed towards methods for developing a maize plant in a plant breeding program where the maize plant of claim 11 is used as a source of breeding material. The language of claims 25-30 makes

clear that the maize plant of claim 11 must be used as breeding material in the breeding program described by claims 25-30.

Plant breeding techniques are well known to individuals skilled in the art. The Specification describes many of these known techniques. (Specification, p. 1, l. 18-p. 7, l. 6). In particular, the specification discusses the role of an inbred maize line in a plant breeding program:

Plant breeding techniques *known in the art and used in a maize plant breeding program* include, but are not limited to, recurrent selection, backcrossing, pedigree breeding, restriction length polymorphism enhanced selection, genetic marker enhanced selection and transformation. The development of maize hybrids in a maize plant breeding program requires, in general, the development of homozygous inbred lines, the crossing of these lines, and the evaluation of the crosses. Pedigree breeding and recurrent selection breeding methods are used to develop inbred lines from breeding populations. Maize plant breeding programs combine the genetic backgrounds from two or more inbred lines or various other germplasm sources into breeding pools from which new inbred lines are developed by selfing and selection of desired phenotypes. The new inbreds are crossed with other inbred lines and the hybrids from these crosses are evaluated to determine which of those have commercial potential. (Specification, p. 3, ll. 18-30) (emphasis added).

As the specification makes clear, one of ordinary skill in the art would know how a maize inbred line is to be used in a plant breeding program. As taught by the specification, the maize inbred is used as a source of germplasm in creating new hybrid lines. It is thus clear from the specification, and to one of ordinary skill in the art, how PH48V would be employed in a plant breeding program.

One skilled in the art would thus recognize that Applicant was in possession of the invention described in claims 1-10, 13-16 and 18-30 as of the filing date of the application. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

C. Enablement regarding Claims 1-10, 13-16 and 18-30

Claims 1-10 remain and claims 13-16 and 19-30 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention for the reasons stated in the Office Action of December 23, 2004. *See* Office Action, p. 4

Applicant respectfully traverses. Applicant reiterates that the claimed F1 hybrid seed is routinely and easily produced by crossing a plant from inbred maize line PH48V with a plant from another inbred maize line. Applicant has described how to produce an F1 hybrid from inbred maize line PH48V. (Specification, p. 3, l. 16-p. 4, l. 25). Applicant has also made a deposit of inbred PH48V that fully enables others to obtain the inbred seed needed to make the claimed F1 hybrids.

Applicant has also provided a working example showing the production of an F1 hybrid produced from the cross of inbred PH48V and inbred PH0KT (*See* Tables 4A-4E, Specification, p. 43-49). The Examiner has shown no evidence as to why this working example does not show enablement of claims 1-10, 13-16, and 18-30, directed to hybrid maize plants, plant parts and seeds produced by crossing maize inbred line PH48V with another maize plant. As shown by Tables 4A-4E, PH48V demonstrates good specific combining ability with other inbreds (*See* Tables 4A-4E, Specification, p. 43-49). One of ordinary skill in the art could therefore use PH48V and another maize inbred plant to create an F1 hybrid, without undue experimentation. This is sufficient to enable claims 1-10, 13-16, and 18-29. *In re Wands*, 858 F.2d at 737.

Applicant further reiterates the arguments regarding the references cited by the Examiner as previously presented in the Amendment of April 20, 2005. Applicant asserts the references relate to segregating populations of seed (Kevern), selection within the segregating populations of seed (Carlone), comparison of synthetic populations (Stuber *et al.*), and the making of all possible crosses including F2, 3-way and backcrosses (Melchinger) to produce a population of seed. In contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. An F1 hybrid as claimed is not a genetically mixed population, but rather is highly homogeneous and reproducible because it is made from the highly homogeneous and reproducible inbred maize line PH48V. (Specification, p. 14, lines 17-18). As stated *supra*, Applicant has provided a working example showing the production of an F1 hybrid produced from the cross of inbred PH48V and inbred PH0KT (*See* Tables 4A-4E, Specification, p. 43-49). This is sufficient to comply with the enablement requirement.

Regarding claims 19-21, the Examiner cites Murray *et al.* and states that "linkage drag is common phenomenon in corn breeding, and the equivalent of 10 backcrosses resulted in the retention of 10% of the unwanted donor parent genome, in contrast to the predicted less than 1% (see, e.g., pages 82-84)." The Examiner further states that with respect to claims 19-24, "one skilled in the art would not know how to make such plant" and "would not know how to use plants exhibiting unknown traits". With respect to claims 25-30, the Examiner states "one skilled in the art would not know how to use said plants with uncharacterized genomes and exhibiting unspecified traits." See Office Action, p. 5.

Applicant respectfully traverses. With respect to Murray *et al.*, the Examiner is referring to a section that is discussing six backcrosses to a specific inbred line, which is not PH48V. Moreover, Murray *et al.* teaches that the very issue of linkage drag cited by the Examiner can be greatly circumvented with the use of molecular markers. Murray *et al.* states: "[t]he longstanding concept of using markers flanking a desirable gene to circumvent these problems (Bartlett and Haldane, 1935) is now practical with RFLP markers. Individuals in which recombination has occurred optimally close to the desired locus can be identified and thus linkage drag can be greatly reduced." (Murray *et al.*, p. 84).

Moreover, the specification teaches on page 4, lines 7-13, that "[b]ackcrossing can be used to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait. This can be accomplished, for example, by first crossing a superior inbred (recurrent parent) to a donor inbred (non-recurrent parent), that carries the appropriate gene(s) for the trait in question. The progeny of this cross is then mated back to the superior recurrent parent followed by selection in the resultant progeny for the desired trait to be transferred from the non-recurrent parent." Further, the specification provides a description of how to backcross traits into PH48V. (Specification, p. 22, l. 1-p. 33, l. 38).

In addition, the specification provides a description of how to backcross traits into PH48V (Specification, p. 20, ll. 16-31) and it is understood by those of skill in the art that backcross conversions are routinely produced and do not represent a substantial change to a variety. The World Seed Organization, on its web site, writes, "[t]he concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents." ASSINSEL, an International breeders

association, has published a position paper that refers to a conversion produced by repeated backcrossing of parental lines of hybrid varieties as a "cosmetic modification". As determined by the UPOV Convention, "essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering" (emphasis added). A copy of the relevant portion of the UPOV Convention and the World Seed Organization web site was attached as Appendix B to an amendment filed December 30, 2002 in the parent case, U.S. Serial No. 09/490,666, now U.S. Patent No. 6,734,348. Thus, it is clear that there is worldwide agreement that by obtaining the seed of a newly developed variety such as PH48V, and by using such seed for repeated backcrossing in accordance with the current claims, one is producing only a cosmetic modification and plagiarizing the work of the inbred inventor.

The ability of one of ordinary skill in the art to effectively use backcrossing to introgress a single gene conversion is also clearly supported by the scientific literature. For example, see Ragot, M. *et al.* (1995) Marker-assisted backcrossing: a practical example, in *Techniques et Utilisations des Marqueurs Moléculaires (Les Colloques, Vol. 72, pp. 45-56* (attached as Appendix 1), and Openshaw *et al.*, (1994) Marker-assisted Selection in Backcross Breeding, Analysis of Molecular Marker Data, pp. 41-43 (attached as Appendix 2). Specifically, Ragot *et al.*, which makes note of the earlier work of Murray *et al.*, demonstrates that "spectacular" progress toward the recurrent parent genotype was obtained with 61 RFLP markers. Ragot *et al.* concludes that "recovery of the recurrent parent genotype could proceed even faster than in the experiment described herein, should the appropriate protocol and resources (population size, number and position of markers) be allocated."

As to claim 22, the Examiner cites Goldman *et al.* and states that "the use of molecular markers to facilitate the identification of chromosomal regions associated with quantitatively inherited traits is hampered by the different linkage maps generated when different breeding lines are used as parents." See Office Action, p. 6.

Applicant respectfully traverses. Goldman *et al.* is discussing the identification of specific loci associated with specific traits, i.e. high and low oil content, in specific strains, specifically Illinois High Oil and Illinois Low Oil. (See, e.g., Goldman *et al.*, p. 908). It

does not discuss the use of molecular markers generally to identify other traits in other lines of maize, let alone PH48V.

Goldman *et al.* does not state that molecular markers can not be used in the identification of specific traits. Instead, Goldman *et al.* discusses the value of using markers in identifying various traits in a maize line. For example, Goldman *et al.* states: "[t]he recent development of molecular marker technology has enabled the association of DNA markers with important agronomic traits such as yield, plant height, and disease resistance." (Goldman *et al.*, p. 908).

Furthermore, the specification teaches multiple ways of introgressing or transforming a maize plant with various genes which encode specific protein products which confer advantageous traits desired in the plant. (Specification, p. 22, l. 1-33, l. 38). This includes the use of markers to aid in the identification, selection and transformation of the maize plant with the desired gene.

Applicant has described how to produce an F1 hybrid from inbred maize line PH48V. In addition, one skilled in the art of corn breeding would know that the F1 plants and seed of claims 1-10, 13-16 and 18-30 can routinely and easily be produced by crossing PH48V with another inbred maize line. Further, one skilled in the art of corn breeding would also know that the maize plants of claims 18-30 can easily be engineered to contain and express foreign genes. Accordingly, Applicant submits that claims 1-10, 13-16, and 18-30 are fully enabled and have fully satisfied the legal standards for enablement.

Rejections Under 35 U.S.C. § 102(b)

Claim 16 is rejected under 35 U.S.C. § 102(b) as being anticipated by each of Kevern (U.S. 5,850,009) and Carlon (U.S. 5,763,755). The Examiner states that because "the claim is drawn to seeds produced on an F1 hybrid plant . . . such progeny are indistinguishable from any known non-exemplified corn plant, including those taught by each of Kevern and Carlon". See Office Action, p. 7.

Applicant respectfully traverses this rejection. Neither Kevern nor Carlon disclose each of the limitations of claim 16. Claim 16 is drawn to an F2 maize seed, which is produced by growing the F1 maize plant of claim 15 and harvesting the resultant maize seed. The F1 maize plant of claim 15 is produced by from the hybrid seed of claim 14,

which ultimately depends from claim 12. Claim 12 requires that the F1 hybrid seed is produced by crossing a first parent maize plant with a second parent maize plant, wherein one or both of the parent maize plants are PH48V.

Neither Kevern nor Carlon teach the seed or plant of PH48V, or an F1 seed or plant produced from PH48V. An F2 hybrid seed produced from an F1 seed which is the result of a cross where PH48V is at least one of the parents will contain at least some of the common structural feature of PH48V which is contained in the F1 seed. Claim 11, drawn to the PH48V maize plant, has been allowed by the examiner. Therefore, because Kevern or Carlon does not teach PH48V, it can not anticipate claim 16.

In light of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections to claim 16 as under 35 U.S.C. § 102(b) as being anticipated by each of Kevern (U.S. Patent No. 5,850,009) and Carlon (U.S. Patent No. 5,763,755).

Summary

Applicant acknowledges that claims 1-15 and 17-30 are deemed free of the prior art. This clearly indicates that maize inbred line PH48V as a whole is considered to be distinguishable from the prior art for the purposes of novelty and non-obviousness.

Applicant also acknowledges that claims 11-12 and 17 are allowed.

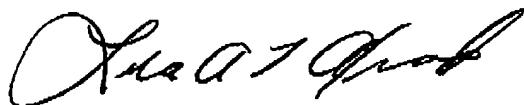
Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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